IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(HOUSTON DIVISION)

GAYATHRI MURTHY, Plaintiff,	§ § §	
v.	§	CASE #: 4:11-cv-00105-KPE
ABBOTT LABORATORIES, Defendant.	§ § §	

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION TO EXCLUDE THE TESTIMONY OF MICHAEL HAMRELL, Ph.D.

Respectfully submitted,

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Plaintiff Gayathri Murthy files the following Response in Opposition to Defendant's Motion to Exclude the Testimony of Michael Hamrell, Ph.D.:

Overview and Summary

Defendant Abbott Laboratories has filed a multitude of purportedly dispositive motions and has inundated the Court with paper and related exhibits [Dkt. #'s 137, 138, 139 and 140]. Plaintiff will respond to each in kind. However, Plaintiff expressly adopts herein all arguments and authorities set forth in her companion responses and briefing.[1]

This case concerns, *inter alia*, Abbott's failure to provide legally adequate warnings about the risks of Humira-induced lymphoma. Second Amended Complaint [Dkt. # 39] at ¶¶ 2-3. But, in addition to the more traditional failure-to-warn components, this case also includes questions of the scope of the duty to warn when patients are serving in experimental as clinical trials for the drug company's ultimate financial benefit.

As Abbott points out in its briefing, Dr. Hamrell has been retained by Plaintiff to address the regulatory aspects of both Humira's labeling and warnings as well as the related clinical trial warnings provided to Plaintiff and her physician upon her inclusion in Abbott's HERO trial. Unsurprisingly, nowhere in Abbott's brief does it inform the Court that Dr. Hamrell's credentials and methodology in "failure-to-warn" cases have been thoroughly vetted under both *Daubert*[2] and *Fry*[3] in other recent judicial opinions. In both instances, under either standard, his testimony was found to be both reliable and admissible. *In re Celexa & Lexapro Products Liab. Litig.*, MDL 1736,

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[1] Such companion briefing includes Plaintiff's Motion for Partial Summary Judgment [Dkt. # 129], Response in Opposition to Defendants Motion to Exclude Causation Testimony Under Federal Rule of Evidence 702, Response in Opposition to Defendant's Motion for Summary Judgment on Causation, and Response in Opposition to Defendant's Motion for Summary Judgment on Failure-to-Warn and Breach-of-Contract Claims.

[2] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

[3] *Frye v. United States,* 293 F. 1013 (D.C. Cir. 1923).

2013 WL 791784 (E.D. Mo. Mar. 4, 2013) and *In Re Humira Litigation: Delores Tietz and Milton Tietz v. Abbott Laboratories*, Case No. L002715 (April 16, 2013), in the Circuit Court of Cook County, Opinion attached as Exhibit 1 at 43:2-44:17.

Nevertheless, it is clear that *Daubert* and its subsequent progeny provide the starting point for the exercise of the Court's discretionary powers. Despite the excessive *Daubert* filings that are *de rigeur* tactics for Abbott,[4] it is important to remember that "*Daubert* did not work an overriding change in federal evidence law, and 'the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system.'" *Barnett v. Eaz-Lift Spring Co.*, 2:03-CV-185-DF, 2005 WL 6735728 (E.D. Tex. Feb. 9, 2005) (quoting *United States v. 14.38 Acres of Land, More or Less, Situated in Leflore County, Miss.,* 80 F.3d 1074, 1078 (5th Cir.1996)). Thus, "the rejection of expert testimony is the exception rather than the rule." FED. R. EVID. 702 advisory committee's note.

Although Abbott does not come right out and say it, their criticisms of Dr. Hamrell are all principally based on the argument that he does not employ "the scientific method." But, as the Advisory Committee notes make clear, "some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular field of expertise." *Id.* And to be clear, there is no novel scientific method or technique at issue with regard to Dr. Hamrell's opinions. Rather his opinions are the result of the application of his extensive and specialized pharmaceutical regulatory experience to the facts of this

[4] *See Maureen E. Calisi v. Abbott Laboratories*, Case #: 1:11-cv-10671-DJC; U. S. District Court for the District of Massachusetts, and extensive citation to *Calisi* throughout Abbott's papers. For background, the *Calisi* case is very similar to the one at bar. Same counsel, same drug, same experts, same injury, same general time frame. Abbott equally buried the *Calisi* court in more than 100 pages of briefing and filed substantially the same motions in *Calisi*. That court has not yet ruled on these motions. Nonetheless, much of the evidentiary record comes from that case. However, Dr. Hamrell did provide a case specific expert report in this case and was deposed a second time in this matter.

case. Thus, it is Rule 702 and *Kumho*[5] that will more closely guide the Court in this instance.

Given Abbott's motion papers, it is important to frame the significance of this particular motion. Abbott has, and continues, to exert great energy in an attempt to highlight and legitimize the "warning" information that was contained in the label at the time of Mrs. Murthy's prescription.[6] If the law defined adequacy as the over simplistic notion that one need only mention a particular risk somewhere in the small print in order to fulfill one's legal duty, then perhaps the inquiry would be at an end. But that is not the law.[7] Nor is it the end of the issues with which this Court must grapple. Abbott has a legal duty to effectively communicate *adequate* warnings about dangers posed by the use of its multi-billion dollar drug. *See* Plaintiff's Motion for Partial Summary Judgment [Dkt. # 129] at 21-22; *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012), reh'g denied (Aug. 17, 2012).

To that end, Dr. Hamrell has been proffered to comment on Humira's regulatory background, labeling, the standard of care in the pharmaceutical industry in general, and the HERO trial in particular. *See generally* Exhibit 2 (Expert Report of Michael Hamrell, Ph.D.). He has been designated to assist the jury with understanding why the information that Abbott trumpets as "adequate" was, in fact, not, as well as how Abbott's marketing efforts undermined whatever words of caution may have been in the label. He does so by the application of his extensive regulatory and

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[5] As this Court recently noted in *Black v. Toys R US-Delaware, Inc.*, 4:08-CV-3315, 2010 WL 4702344 (S.D. Tex. Nov. 10, 2010), "the *Daubert* "test of reliability is 'flexible,' and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case'" *citing Kumho Tire Co., Ltd. V. Carmichael,* 526 U.S. 137, 150-51 (1999).

[6] *See* Abbott's Second Amended Answer [Dkt. # 116 at 2-4, 8-10, 18-22, 23-25, 26-28, 29-32]; Motion to Exclude the Testimony of Michael Hamrell, Ph.D. Under Federal Rule of Evidence 702 [hereinafter "Abbott's Motion"] at 6; and its expert report of Dr. David Feigal [Dkt. # 124, Ex. 4 at 24-25].

[7] *See e.g., McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006)(Reversing summary judgment despite mention of specific risk in drug label because of evidence that the label was misleading regarding the actual risk; "the default Texas rule" is to allow the jury to decide such ambiguity.).

industry experience to the evidence in this case.

By way of background, Dr. Hamrell is a highly experienced pharmacologist and toxicologist who has previous experience as both a reviewer for the FDA and as a Regulatory Affairs Section Chief at the National Institute of Health ("NIH"). He is currently the president of a pharmaceutical industry consulting firm. In that capacity, he has been retained as a consultant for a leading clinical trial research organization that Abbott itself routinely employs. More significantly, and unsurprisingly not mentioned by Abbott in its papers, *Abbott* has employed Dr. Hamrell as a regulatory consultant on multiple occasions during the past 10 years. Exhibit 3 at 132:18-133:12 (Deposition of Michael Hamrell, Ph.D. taken in *Maureen E. Calisi v. Abbott Laboratories*; Case #: 1:11-cv-10671-DJC; In the U. S. District Court for the District of Massachusetts).

Yet, despite Abbott's recognition of, and dependence upon, Dr. Hamrell's expertise for its own pharmaceutical development and regulatory compliance, evidently in the litigation arena, the very same methodology, experience and judgment that he employs when working for industry is unreliable. It is the epitome of inconsistency for Abbott to employ Dr. Hamrell for his regulatory expertise "in the real world," then come into this Court and exert 18 pages attacking him. The Court should not harbor such litigation driven tactics and should deny Abbott's motion in its entirety.

Arguments and Authorities

I. DR. HAMRELL IS WELL-QUALIFIED TO OPINE ON THE ADEQUACY OF HUMIRA'S LABELS AND THE HERO CLINICAL TRIAL.

As the Court decides the admissibility of Dr. Hamrell's testimony, there are clear legal principles that will guide its analysis.[8] Abbott passingly criticizes Dr. Hamrell's qualifications. It exerts much greater energy with respect to attacking his "methodology" and the relevance of his

[8] Although the legal standards the Court will employ in this analysis are covered in much greater detail in Plaintiff's concurrently filed Response in Opposition to Defendant's Motion to Exclude Causation Testimony under Federal Rule of Evidence 702, a few additional relevant principles need to be raised herein.

opinions. That being said, Plaintiff admittedly bears the burden of establishing the reliability of her proffered expert testimony by a preponderance of the evidence. FED. R. EVID. 702 advisory committee's note (citing *Bourjaily v. United States*, 483 U.S. 171 (1987)). And because it is Plaintiff's burden, we start with qualifications.

A. Dr. Hamrell's Qualifications. Although Abbott comments on Dr. Hamrell's qualifications in a disparaging manner, they do not expressly challenge them. Regardless, any concerns regarding Dr. Hamrell's qualifications should give this Court little pause. An expert can be qualified by "knowledge, skill, experience, training, or education" to offer opinions that will assist the trier of fact. FED. R. EVID. 702. *See also Kumho, supra,* 526 U.S. 137, 151. The Fifth Circuit teaches that both Rule 702 and *Daubert* are liberally interpreted in favor of the admission of expert testimony. *See Guzman v. Mem'l Hermann Hosp. Sys.*, CIV.A. H-07-3973, 2008 WL 5273713 (S.D. Tex. Dec. 17, 2008) citing *United States v. Marler,* 614 F.2d 47, 50 (5th Cir. 1980).[9]

Whether an expert is qualified depends on if the witness has "such knowledge or experience in [his] field or calling as to make it appear that his opinion or inference will probably aid the trier in his search for truth." *United States v. Hicks*, 389 F.3d 514, 524 (5th Cir.2004). This Court well understands the requisite standards: "[d]ifferences in expertise bear chiefly on the weight to be assigned to the testimony by the trier of fact, not its admissibility." *Interplan Architects, Inc. v. C.L. Thomas, Inc.*, 4:08-CV-03181, 2010 WL 4065465 (S.D. Tex. Oct. 9, 2010).[10]

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[9] *Accord Levin v. Dalva Bros., Inc.*, 459 F.3d 68, 78 (1st Cir. 2006)("Rule 702 has been interpreted liberally in favor of the admission of expert testimony.)*; In re TMI Litig*., 193 F.3d 613, 664 (3d Cir. 1999) amended, 199 F.3d 158 (3d Cir. 2000)(Qualification requirement should be liberally interpreted to include "a broad range of knowledge, skills, and training."); *Tuf Racing Products, Inc. v. American Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000)("Anyone with relevant expertise" may qualify as an expert witness if testimony will be helpful to judge or jury.).

[10] *Accord Austin Firefighters Relief & Ret. Fund v. Brown*, 760 F. Supp. 2d 662, 678 (S.D. Miss. 2010)("[M]ost arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility."). *See also Bartlett v. Mut. Pharm. Co., Inc.*, 742 F. Supp. 2d 182, 195 (D.N.H. 2010)("[P]harmacologist who has held high-ranking jobs with the FDA and three major drug companies" was qualified to testify about the standards of care within the pharmaceutical industry.).

With the law in mind, we now examine Dr. Hamrell's qualifications. His report and attached *curriculum vitae* detail Dr. Hamrell's extensive knowledge, skill, experience, training, and education. Dr. Hamrell earned a BS in Biochemistry from the University of California, Los Angeles in 1973 and a Ph.D. in Pharmacology[11] from the University of Southern California in 1977. Exhibit 2 at 2-5; 20-38.[12] He was awarded a Regulatory Affairs Certification from the Regulatory Affairs Professional Society ("RAPS")[13] in 1996 and was elected a RAPS fellow in 2009. *Id.*

Over the course of the last 30 years, Dr. Hamrell has been involved in virtually "all aspects of product development in the pharmaceutical, biotech, and medical device industry." *Id.* at 3. He has more than 25 years of experience in drug, biologic, and medical device regulatory affairs. *Id*. He is past Editor-in-Chief of the Drug Information Journal (2005-2010) and on the Editorial Board of the Clinical Trial Magnifier (2009-), Clinical Trial Advisor (1999-), Applied Clinical Trials (1990-), Regulatory Affairs FOCUS (1990-2000),[14] and the Drug Information Journal (1995-2001). *Id*. at 23. Additionally, he was the Editor-in-Chief for the DIA[15] Forum (2001-2004) and on the DIA Advisory Counsel for North America (2000-2007).

Dr. Hamrell started his career as an Assistant Professor of Pharmacology at McGill University in Montreal, Canada. *Id*. at 3-5; 22. From academia, he moved into the pharmaceutical industry as a Drug Registration Manager in 1982 with Anaquest/BOC Group. *Id*. at 4; 22.

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[11] Pharmacology is a science discipline that combines medicine and biology in the study of drug action.

[12] The page references are to the pdf pages vice the actual pages of the report.

[13] "The Regulatory Affairs Professionals Society (RAPS is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products." *See* http://www.raps.org/.

[14] This journal is the "flagship" publication for regulatory professionals around the world. *See* http://www.raps.org/focus-online/about-regulatory-focus.aspx.

[15] DIA is a neutral non-profit association for therapeutic innovation and regulatory science. *See* http://www.diahome.org/Home/About-DIA.

In 1985, Dr. Hamrell left Anaquest/BOC and began work as a pharmacologist-reviewer in the Center for Drug Evaluation & Research at the Food and Drug Administration ("FDA"). *Id*. at 3-4; 21. During the five years he spent at the FDA, Dr. Hamrell worked in both the Division of Bioequivalence (1985-1988) and the Division of Antiviral Drug Products (1988-1990). *Id.* At the FDA his work focused on both generic drugs and drugs for serious and life threatening illnesses. *Id*. He was the primary reviewer for more than 50 Investigational New Drug Applications[16] and New Drug Applications.[17] *Id.* at 3-4; 21. He also reviewed more than 200 bioequivalence studies for major drug products. *Id*. This experience provided him broad knowledge of FDA regulatory requirements. *Id*. He authored a major policy paper for the FDA on bioequivalence that received peer reviewed publication and industry wide dissemination as well as an authoritative Task Force Report on bioequivalence. *Id*.

Additional responsibilities for Dr. Hamrell while at the FDA included clinical trial and clinical trial data review (Exhibit 3 at 17:4-14; 19:6-7; 36:16-21); the preparation of clinical trial data and safety summaries (Exhibit 2 at 2); the review of prescription drug labels for the FDA (Exhibit 3 at 20:18-21:7); participation in the drafting of warning information and labeling for both generic and branded drugs (*Id*. at 21:11-22:1; 52:16-24);[18] meeting with industry/pharmaceutical companies regarding labeling (Exhibit 2 at 21; Exhibit 3 at 34:21-24); advising pharmaceutical companies on

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[16] The IND is generally the first step towards seeking FDA approval for marketing a new drug to the public. *See* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm.

[17] "The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S." *See* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm.

[18] To be fair, although Dr. Hamrell is "sure" he participated in drafting precaution and warning information for prescription drug labels, due to the passage of more than 20 years, in deposition he was unable to recall and/or identify with specificity a specific drug. *Id*. at 17:17-21; 26:18-20 ("I can't give you an example. It was 25 years ago. I don't recall. I worked on probably 300 drugs while [at FDA]....I participated in drafting lots of labels, but I don't recall any one specific product."). More *anon*.

application requirements (Exhibit 2 at 21); preparation of guidance for pharmaceutical companies on drugs (*Id.*); and monitoring of post-marketing drug safety data (Exhibit 3 at 41:12-15; 42:1-6).

Dr. Hamrell left the FDA in 1990 and joined the NIH as the Chief of the Regulatory Affairs Section for the Division of AIDS/NIAID. Exhibit 2 at 3; 21. As the senior regulatory affairs person for his division, Dr. Hamrell was responsible for all regulatory and compliance activities for a network of multi-center groups conducting clinical drug trials for AIDS treatment. *Id.* He managed a staff in the submission of more than 50 active INDs each year while at NIH as well as coordinated all regulatory aspects for four multi-center trials including drugs and biologics[19] being carried out at approximately 200 different worldwide clinical sites. *Id.* Further, while at NIH, Dr. Hamrell was a liaison for the pharmaceutical industry and provided information to NIH staff on regulatory issues concerning clinical trials. *Id.*

From 1992-1993, Dr. Hamrell was the Director of Worldwide Regulatory Affairs for a biotech company named Vestar. *Id.* at 3; 20. He was responsible for all worldwide regulatory activities including all regulatory submissions for the company. *Id.* He provided guidance to the company *vis-à-vis* all regulatory requirements for product registration, marketing, Good Clinical Practice,[20] safety and adverse event reporting. *Id.* at 3; 20. In addition to his pharmacological and toxicological responsibilities, he also was a liaison with government and industry representatives regarding marketing requirements. *Id.*

Additionally, while at Vestar, Dr. Hamrell drafted safety labeling for a series of new drugs. Exhibit 3 at 49:24-52:7. At least two of these drugs went on to FDA approval. *Id.* He participated

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[19] As the Court is by now undoubtably aware, Humira is a biologic prescription drug.

[20] Good Clinical Practice is a series of laws and/or regulations utilized by the FDA that primarily concern the protection of humans in clinical research and is "universally" recognized as a critical requirement in doing same. *See* http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

in FDA meetings regarding safety labeling, orchestrated company presentations to FDA advisory committees, and participated in the advisory committee for a Vestar product. *Id*.

In 1994, Dr. Hamrell established, and is currently president of, Moriah Consultants. Exhibit 2 at 2-3; 20. This company is a professional consulting firm that focuses on comprehensive regulatory affairs consulting and training for the pharmaceutical, biotechnical, and medical device industries. *Id*. While at Moriah, Dr. Hamrell has worked on drafting safety labels. Exhibit 3 at 121:1-6. He has additionally consulted with Paragon Biomedical, a contract research organization, that Abbott's counsel holds to be "one of the leaders" and "best players" "in the industry" (*Id*. at 47:19-48:28) and who also frequently collaborates with Abbott in Humira clinical trial work. *See e.g.,* http://www.clinicaltrials.gov/ct2/show/NCT00710580.

More significantly, Dr. Hamrell has personally been retained by Abbott as a consultant for a number of projects during the last 10-12 years. Exhibit 3 at 132:18-133:12. Included in this work for Abbott was regulatory consulting with regard to Abbott's prescription drug products. *Id*. at 233:19-234:22. Although due to the passage of time, Dr. Hamrell could not recall the specific Abbott drugs he worked on, he did specifically recall working on projects for Abbott's regulatory affairs department. *Id*. He additionally worked on a medical device called Xience that was being developed by a company owned by Abbott. *Id*. at 237:9-238:12.

In addition to Dr. Hamrell's extensive, detailed, and relevant regulatory experience outlined above, he has also extensively published. Exhibit 2 at 24-28. He authored two seminal papers at the FDA. *Id*. at 4. He has also published regarding prescription drug labeling. For example, Hamrell, MR, *Current Regulations and Practices for Adverse Event Reporting: Implications for Labeling*, Drug Information Journal,[21] Vol. 34, pp. 975-980, 2000 (attached hereto as Exhibit 4), has

[21] Drug Information Journal is a peer-reviewed publication. *See* http://www.sagepub.com/journals/Journal202090.

a section entitled "Labeling Requirements for New Drugs." *Id*. at 978-979. Therein, Dr. Hamrell discusses various federal drug regulations, requirements for prescription drug warnings, precautions, and adverse events needed for "safe and effective use of the drug." *Id*. He also discusses in this peer reviewed publication how drug manufactures may make changes to their labels in order to comply with federal regulations as well as how to disseminate safety information to doctors. *Id*.

Plaintiff will not belabor the point, but a quick review of the various publications also reveals that Dr. Hamrell has published on the history of the FDA (Exhibit 2 at 25); clinical trials (*Id*.); and biologics and the regulation of combination products (*Id*. at 26).

Dr. Hamrell has additionally taught courses in regulatory affairs[22] and has extensively presented to his professional regulatory affairs peers. This experience is chronicled in detail in his *C.V*. on pages 29-38 of Exhibit 2.

By any fair measure, Dr. Hamrell is extensively qualified by virtue of "knowledge, skill, experience, training, and education" to offer opinions about U.S. regulatory matters concerning prescription drug labeling, clinical trials, and the standard of care in the pharmaceutical industry.

B. Abbott's Thinly Veiled Criticisms of Dr. Hamrell's Qualifications are Overstated and Meritless. Abbott does not formally object, or otherwise argue, that Dr. Hamrell is unqualified to render regulatory and warnings opinions in this case. Nor could they given his "impressive credentials," "[extensive publications] on regulatory issues," and specialized expertise. *In Re Celexa, supra*, 2013 WL 791784 at 4. Rather, the thrust of Abbott's commentary on pages 4-5 of its motion is that Dr. Hamrell is in some way not qualified to opine on regulatory matters

[22] Highlights include the following: US Regulatory Affairs (IBRD-ROSTRUM - a pharmaceutical research organization); Medical Device Development and Regulation (University of Southern California - School of Pharmacy); Combined Regulatory Training Course (Massachusetts College of Pharmacy & Health Sciences); Introduction to Regulatory Affairs/Fundamentals of Product Development/Clinical Research Seminar (University of North Carolina Wilmington, School of Nursing); Regulatory Strategies in the Development of Drugs and Biologics (George Washington University, School of Medicine).

concerning drug labeling based on legally irrelevant criticisms that have zero basis under the law.

Abbott's counsel take great umbrage with Dr. Hamrell because he could not recall with specificity events transpiring 20-25 years while he worked at FDA. Nor do they have any patience for the fact that Dr. Hamrell worked on more than 300 different drugs as well as extensive additional prescription drug work in the intervening years. Exhibit 3 at 17:17-21 ("It was 25 years ago...I worked on probably 300 drugs while I was [at FDA]."). Unfortunately for them, depositions are not memory tests. But they certainly cannot and do not deny his peer reviewed publications that stem from his work at FDA. Exhibit 2 at 3-4, 21; Exhibit 4 hereto.

Further, what Abbott equally fails to relay to the Court is the fact that Dr. Hamrell was part of the collaborative team that drafted drug labels while at FDA, to include warnings:

> "As I said, the drafting of the label is a collaborative operation between all the members of the review team, and so I don't recall who drafted what parts of what labels. It's a collaborative effort with the company and the FDA....it's a collaborative effort between the whole team of people...as I said, no one person drafts a label, so it's a collaborative effort.

Exhibit 3 at 27:17-28:1;28:21-22; 29:3-4. Abbott's own FDA warning expert verified the accuracy of Dr. Hamrell's testimony: "The FDA employs a staff that is experienced in crafting language for drug labels that is clear and understandable....This staff works with pharmaceutical manufacturers to ensure that product labeling adequately conveys these risks and benefits....." Dkt. # 124, Ex. 4 at 9. Although the passage of 25 years prevented Dr. Hamrell from identifying which of the 300 drugs he worked on, it is still undeniably clear that he was part of the FDA "staff" tasked with reviewing and drafting drug labels.

Significantly, Abbott does not dispute that Dr. Hamrell actually worked at the FDA. Nor do they dispute that he actually worked on reviewing and drafting drug labeling while at the FDA. Nor do they make any mention of Dr. Hamrell's time at the NIH where he was a Chief of the Regulatory

Affairs Section for one of its divisions. Nor do they dispute his certification and fellowship in the internationally recognized RAPS. Nor do they dispute his leadership roles and editorial positions for a variety of industry specific, peer-reviewed publications dealing with regulatory matters and labeling. Nor do they mention, much less dispute, his peer-reviewed publications dealing with prescription drug labeling requirements. Nor do they dispute that he actually identified two drugs he worked on in industry. Nor, in fact, do they dispute that he worked for Abbott on multiple occasions.

Equally true is that Abbott fails to inform the Court that the basis for Dr. Hamrell not specifically identifying some of the drugs he has worked on is due to confidentiality constraints. Thus, they unfairly chide Dr. Hamrell because he was unwilling to violate confidentiality requirements placed upon him by the FDA and the private pharmaceutical companies that retain him. Exhibit 3 at 30:3-21;121:1-13. This is hypocrisy. Abbott cast a veil of secrecy over this litigation by requiring confidentiality orders prior to exchanging documents. [Dkt. # 81]. They have required that Plaintiff file documents under seal and bind witnesses to the terms of the protective order before examining Abbott documents. Abbott, rabidly guards patents, trade secrets, and developmental work.[23] Abbott cannot claim clean hands with criticisms concerning confidentiality.

II. DR. HAMRELL'S OPINIONS ARE RELIABLE AND HIS METHODOLOGY IS SOUND.

Predictably, Abbott opens its substantive argument with attacks on Dr. Hamrell's opinions as unreliable and "pure *ipse dixit*."[24] Equally predictable is that it attempts to impliedly make testing

[23] The Court need look no further than the fact that Abbott's new start up company, AbbVie (that was formed in the wake of the monumental financial success of Humira and that will retain the rights to Humira) has already initiated litigation to protect its trade rights. *See* http://www.chicagobusiness.com/article/20120906/NEWS03/120909909/abbvie-starts-suing-even-before-it-launches.

[24] Plaintiff responds to the general causation arguments underlying Dr. Hamrell's opinions identified by Abbott in FN 17 of their brief in the concurrently filed Response in Opposition to Abbott's Motion to Exclude Causation Testimony.

and peer-review publication the *sine qua non* of admissibility. This is not the law.

Fifth Circuit case law is clear: "the reliability analysis must remain flexible: not every *Daubert* factor will be applicable in every situation; and a court has discretion to consider other factors it deems relevant." *Guy v. Crown Equip. Corp.*, 394 F.3d 320, 325 (5th Cir. 2004) citing *Kumho,* 526 U.S. at 151. This Court is well aware of this flexible standard:

> The *Kumho* Court noted that the *Daubert* 'test of reliability is 'flexible,' and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case.'...The Court's role is not to mechanically apply the *Daubert* factors, but 'to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.' Therefore, the 'law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination.'"

Black, supra, 2010 WL 4702344 at 3 (Internal citations omitted). *See also Jones v. Halliburton Co.*, 4:07-CV-2719, 2011 WL 1841148 (S.D. Tex. May 13, 2011)(Ellison, J.).

As the advisory notes to Rule 702 make clear, "some types of expert testimony will not rely on anything like a scientific method." FED. R. CIV. P. 702 Advisory Committee Note. It is perfectly reliable for an expert to draw a conclusion from a set of observations based on extensive and specialized experience. *Black,* 2010 WL 4702344, 4 citing *Kumho,* 526 U.S. at 156. *See also Pipitone v. Biomatrix, Inc*., 288 F.3d 239, 247 (5th Cir.2002)("Expert's testimony [can be] based mainly on his personal observations, professional experience, education and training."). The key analysis is whether the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Black, supra,* 2010 WL 4702344, 3.

Neither testing nor peer-reviewed publication of an expert's proffered opinions is the *sine qua non* of admissibility. *Id. at 4* citing *Pipiton, supra* (error rate not relevant when opinion based on observations and professional experience.). *See also Toisa Ltd. v. CAMAC Int'l Corp.*, CIV.A.

H-10-04177, 2011 WL 6176207, 2 (S.D. Tex. Nov. 30, 2011). More importantly for this case, and contrary to Abbott's arguments, is that a proposed warning not only need not be tested, but it also need not have gained general acceptance in either industry or science to "survive *Daubert*." *Hankins v. Ford Motor Co.*, 3:08-CV-639-CWR-FKB, 2011 WL 6291947 (S.D. Miss. Dec. 15, 2011)(Admitting expert warning testimony despite arguments that proposed warning must be tested.). *See also Watkins v. Telsmith, Inc.*, 121 F.3d 984, 990 (5th Cir. 1997) citing *Cummins v. Lyle Indus.*, 93 F.3d 362, 369 (7th Cir. 1996)(Testing is not an absolute requirement under Rule 702.).[25]

Dr. Hamrell's expert report specifically identifies the substantive facts, *i.e.,* the Humira labels (and the warning information contained therein) that he reviewed in formulating his opinions. Exhibit 2 at 13-19, 39-40. He also identifies the Abbott internal documents and company 30(b)(6) depositions he relied upon in reaching his conclusions. *Id*.[26] He reiterated relying upon this evidence in deposition. Exhibit 5 at 39:25-40:3 (Deposition of Dr. Michael Hamrell).

Further, Dr. Hamrell also specifically identified the internal Abbott documents and his reliance upon Abbott testimony that unequivocally reflect that lymphoma was a known risk of Humira. Exhibit 2 at 14-18; Exhibit 5 at 40:8-9. He discussed how the warning information contained in the Humira label and HERO informed consent was inadequate and confusing with respect to providing meaningful information regarding the risk at issue and how the specific doctor

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[25] *Accord Barnett v. Eaz-Lift Spring Co.*, 2:03-CV-185-DF, 2005 WL 6735728 (E.D. Tex. Feb. 9, 2005)(Denying motion to exclude warnings expert despite arguments that the expert's methodology was simply reviewing the warning in-question and offering opinions.).

[26] *E.g.,* "Dr. Medich in his deposition admitted that these data, included in the Integrated Summary of Safety submitted to FDA in 2002 indicate an increased rate of malignancies compared to placebo patients in the Humira studies." *Id*. at 16. "This approach [of not disseminating a Dear Healthcare Professional warning on this risk] is inconsistent with the testimony of Abbott company employees. Dr. Kent indicated in his deposition that the conservative approach would have been to provide the information to the physicians and let them decide whether there is a drug related risk." *Id*. at 18.

in this case was confused about this risk based on review of his deposition testimony. Exhibit 2 at 14-18. He additionally provided his reasoning for these opinions. *Id.*[27] He further described how a proper warning educates and provides meaningful information about the risk posed by the medication, *separate and apart* from the underlying disease. The main problem with the warnings in this case is that Abbott deliberately blamed the risk of lymphoma on the "disease", *i.e.*, RA, and purposefully evaded the critical question of whether the drug Humira exacerbated that risk. Dr. Hamrell explained:

> The language there talks about patients in clinical trials without identifying just patients with rheumatoid arthritis and it says increased risk,·but it doesn't put any quantification on it. It doesn't talk about -- it doesn't provide opportunity for someone to draw any conclusions as to whether the ·drug -- taking the drug while having rheumatoid arthritis adds any risk.· It only talks about the risk relative to the general population for people with rheumatoid arthritis.

Exhibit 3 at 129:12-130:1; 154:5-11; *see also* Exhibit 2 at 13-18. He used Abbott documents and sworn testimony from Abbott scientific Rule 30(b)(6) deponents as the factual basis for all of these opinions. Should the Court desire more, Dr. Hamrell further explained the reasoning behind his criticisms of the warning information in his second deposition:

> "The label still states that the potential role of TNF-blocking therapy in the development of malignancies is not known. Abbott and individuals who are experts from Abbott stated that they were aware of risks associated with the development of malignancies following TNF-blocking therapy. So the section is not completely accurate. And it doesn't really reflect the knowledge and information...so I'm criticizing for the lack of complete information."

Exhibit 5 at 48:6-49:4.

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[27] *E.g.,* "At the time of approval, Humira was only approved for use in patients with RA. Stating that there was a higher incidence of lymphoma in the clinical trials compared to the general population and that RA patients are also at an increased risk for lymphoma does not allow any conclusion as to whether Humira increases the risk of lymphoma...Concluding that the 'potential role of TNF-blocking therapy in the development of malignancies is not known' adds no clarity to the information in the label. If Abbott was aware of an elevated risk, as they appear to have been, this should have been clearly relayed in the label." *Id.*

In this regard, Dr. Hamrell's criticisms dovetail with the actual prescribing physician's confusion: "...I don't know at this point whether – or what is the right answer." Exhibit 6 at 193:2-4 (Deposition of Jovan Popovich, M.D.). The law does not require plaintiff or her expert to write the adequate warning that Abbott should have given. But, Dr. Hamrell did propose a better warning. His proposed alternate warning "provides context for someone to evaluate the risk of someone taking Humira versus the risk of somebody with just RA compared to the general population." Exhibit 5 at 58:4-10. And it directly warns about an elevated risk of lymphoma based strictly on the use of Humira. Exhibit 2 at 15-16. This is the exact information that doctors like Dr. Popovich wanted to know. Exhibit 6 at 211:24-13 ("If they were aware that they are associated, I would definitely want to know.").

Dr. Hamrell's methodolgy in arriving at these opinions is as follows:

> "Well, when I'm offering opinions, whether it's a legal case for one of my clients or a project I'm working on, I review all the information, documents, data, whatever is available in context of what the project is, and I review that information, I review relevant appropriate regulations, guidances, and other things that I may refer to. And I use that along with my experience and knowledge as a regulatory professional, as a pharmacologist and a scientist in forming my opinions."

Exhibit 5 at 75:10-22.

When asked about how he came to his conclusions with regard to providing "meaningful" information to doctors and patients, Dr. Hamrell made clear that he applied the same type of methodology and analysis he utilized both when he worked at FDA as well as when he worked in industry. Exhibit 3 at 131:20-132:11. And when he worked for Abbott:

> Q Which experts in the field use this term "meaningful"?
>
> A Anybody who works in this field.· It's a standard I apply when I work with companies, when I am either helping write labels or develop clinical trials, doing work to evaluate the regulatory case (inaudible) for a product. It's the same standard I used when I was a consultant for Abbott for a number of years, and over three or four different projects, that your company thought

> was adequate when I used that standard when I did consulting work for Abbott.

Id. at 132:12-132:22. *See also* Exhibit 5 at 75:10-22. Clearly, Dr. Hamrell employed the "same level of intellectual rigor" in this case as he did when working for industry.

Additionally, despite contentions to the contrary, Dr. Hamrell did, in fact, conduct a "survey" on Abbott's warning and offers evidence that doctors did not have enough information. He surveyed the testimony of the prescribing physician and his interpretation of the warning information provided to him by Abbott. Exhibit 2 at 15. Any fair reading of Dr. Popovich's deposition reveals his confusion about the risk of lymphoma posed by use of the drug.[28] Dr. Popovich's confusion was another data point relied upon by Dr. Hamrell to support his opinion that the operative label and HERO information provided to him did not provide a clear, meaningful warning to doctors and patients. *Id.* at 14-16;[29] [Dkt. # 129 at ¶¶ 18-26].

Abbott equally chastises Dr. Hamrell for offering no commentary on the FDA actions. Abbott's Motion at 12.[30] What FDA did, or did not do, is *irrelevant* to Dr. Hamrell commenting on the actual information that was provided to doctors and patients. For it is Abbott's undeniable responsibility to clearly and unambiguously warn about dangers posed by the use of its drug, irrespective of FDA action or inaction: "Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears

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[28] This testimony is covered at length in Plaintiff's Motion for Partial Summary Judgment. Plaintiff, hereinafter "MPSJ." We respectfully refer the Court to Dkt. #129 at ¶¶ 15-29 for the references.

[29] Compare this with Dr. Popovich's testimony and the informed consent document stating the risk is "unknown." Exhibit 6 at 201:2-11;213:3-214:11.

[30] Although it need not be covered herein, this argument is a thinly veiled preemption argument. *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009) makes clear that the drug company is always primarily responsible for the labeling and safety of its drug products. *Accord In re Prempro Products Liab. Litig.*, 586 F.3d 547, 563 (8th Cir. 2009)("The Supreme Court's recent decision in *Wyeth v. Levine,* 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), has foreclosed this preemption argument.").

responsibility for the content of its label at all times." *Wyeth, supra*, FN 30, 555 U.S. at 570.

Abbott's criticisms of Dr. Hamrell's HERO opinions fair no better. Rather than being "devoid" of either regulatory or factual support, the record reveals a much different truth. Dr. Hamrell's expert report cites relevant clinical trial regulations. Exhibit 2 at 15, 17. He also articulated knowledge of additional relevant regulations that underscore and support his opinions despite Abbott's counsel's best efforts to surprise him. Exhibit 5 at 76:17-78:4. More fundamentally, irregardless of *how* information was provided to Dr. Popovich, the crux of Dr. Hamrell's HERO opinions is that Abbott failed to clearly and unambiguously warn him and his patients that the use of Humira itself increases the risk of lymphoma in RA patients. Exhibit 2 at 15-16. They failed to do so despite their knowledge of the risk and their legal responsibility to do so.

Additionally, while Abbott maligns Dr. Hamrell's citation to 21 C.F.R. § 312.55 (requiring clinical trial sponsors to provide clinical investigators with updated safety information), this regulation is particularly relevant in this case. First, while Dr. Popovich had some level of awareness of the discussion concerning use of TNF-inhibitors and lymphoma, he was unclear if there was any true causal link between the two. FN 29, *supra*. Thus, the point is that Abbott had the ability and regulatory means for providing Dr. Popovich clear guidance about the true risk of lymphoma for HERO patients. They simply failed to do so. Significantly, they failed to do so despite the fact that during the very time period leading up to Mrs. Murthy's enrollment in HERO, Abbott *was* confidentially informing sales representatives, including those calling on Dr. Popovich, of a true risk. However, it was not so informing doctors – including Dr. Popovich. MPSJ at ¶¶ 24-25. This was important to both Dr. Popovich and Dr. Hamrell in his opinions. Exhibit 2 at 15-18.

The cases cited by Abbott are off-point and readily distinguishable. Unlike *Interplan Architects, Inc. v. C.L. Thomas, Inc.*, 4:08-CV-03181, 2010 WL 4065465, 18 (S.D. Tex. Oct. 9,

2010) where this Court excluded a CPA for failing to articulate how his *accounting skills* directed an analysis of the degree to which store layout can effect shopping behavior, Dr. Hamrell readily voiced how his FDA and private regulatory expertise allowed him to analyze Abbott's internal understanding of risks and contrast that to what it was telling physicians and patients. Additionally, in *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987), expert exclusion was upheld based on *Rule 703* and unreliable data underlying the opinion. Unless Abbott contends that its own data, documents, and testimony from company scientists that Dr. Hamrell relied upon is unreliable, this case is inapposite to the facts before the Court. So, too, *Moore v. P & G-Clairol, Inc.*, 781 F. Supp. 2d 694, 700 (N.D. Ill. 2011) where an organic chemist with no background or training in any field related to design of warnings, "the most minimal experience" in what should appear in a relevant warning, and no experience in how to interpret such a warning, was excluded from a products case involving allergic reaction to hair dye.

Moreover, although Abbott levels the same methodological criticisms at Dr. Hamrell's proposed alternate warnings, the truth of it is that the same legal analysis applies to it as to his other opinions. There is no requirement for publication, testing, or general acceptance. Rather, the fact that he offered a proposed warning illustrates the reliability and admissibility of his testimony.

Dr. Hamrell's methodology is the application of his 30 years of regulatory experience to the internal Abbott documents, deposition testimony of Abbott employees, and the testimony of the prescribing physician in this case. He "employ[ed] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho,* 526 U.S. at 152. His opinions are not *ipse dixit* as Defendant argues. Nor are they speculative or based on speculative facts. But rather, they are the proper and reasoned application of his expertise and experience to the facts of this case. As such, they are wholly and properly admissible.

III. DR. HAMRELL'S OPINIONS REGARDING PATIENT WARNINGS ARE RELEVANT AND ADMISSIBLE.

The main thrust of Abbott's arguments in this section of its motion concern *Centocor, supra,* and Abbott's purported learned intermediary defense. Abbott's motion at pp. 14-15. Plaintiff has fully addressed the lack of applicability of *Centocor* and the learned intermediary doctrine in her MPSJ and concurrently filed Response in Opposition to Abbott's Failure-To-Warn and Breach of Contract Claims. We respectfully refer the Court to that briefing. Suffice to say that under either a direct-to-consumer advertising exception, or agency theory, the warnings provided to Plaintiff are utterly relevant and will assist the trier of fact with the unique facts of this case.

Abbott next cites a series of cases that purportedly support its arguments. However, rote citation to a couple of cases that involve clinical trials without more critical inquiry cannot carry the day for Abbott. Moreover, if the Court finds the learned intermediary doctrine inapplicable in this instance, then these cases are all inapposite. Nevertheless, each is easily distinguishable.

In *Kernke v. The Menninger Clinic, Inc.*, 173 F. Supp. 2d 1117, 1122 (D. Kan. 2001), the plaintiff's 1) did not dispute or present evidence that the drug company should have "taken additional precautions," 2) did not dispute or present evidence that the drug company provided all relevant warnings to the doctors, and 3) presented no proximate cause evidence to show that a different warning would have changed the outcome. In this case, Plaintiff has unequivocally and decidedly contested all three points as well as presented contrary evidence to rebut each.

Sykes v. United States, 1:10-CV-688, 2011 WL 3739017 (S.D. Ohio July 22, 2011) was a Rule 12(b)(6) ruling that does not touch on expert issues.[31] Setting that aside, the ruling was based

[31] In fact, *Kernke, supra*, also did not concern *Daubert.*

on Ohio law. *Id.* at 17.[32] In any event, Dr. Hamrell has made clear that it was Abbott's duty to inform any study monitors or Dr. Popovich about the actual risk at issue. Exhibit 5 at 21:13-22:3 (Study monitor relies upon "the [drug company] who has the most knowledge about the product to provide them information that should reasonably be communicated to a subject."). Abbott does not dispute this. And they failed to do so in this case. Thus, without truthful and accurate information, neither a study monitor nor a clinical investigator is able to obtain a proper informed consent through no fault of either the doctor or the study monitor.[33]

Because Abbott failed to provide such accurate and complete warning information to either the study monitor or the clinical investigator, Dr. Hamrell's opinions regarding warnings to patients are relevant to the Jury's considerations of the facts of this case. The Court should so allow them.

IV. OPINIONS REGARDING ABBOTT'S VIOLATION OF THE "STANDARD OF CARE" ARE RELIABLE.

Both the Fifth Circuit, and others, have looked favorable on the admissibility of industry custom testimony from expert witnesses. *See e.g., First United Fin. Corp. v. U.S. Fid. & Guar. Co.*, 96 F.3d 135, 138, n.2 (5th Cir. 1996)("Not only is expert testimony on loan procedures, industry custom, and prudent conduct permissible..."); *Kona Tech. Corp. v. S. Pac. Transp. Co.*, 225 F.3d 595, 611 (5th Cir. 2000)("Prudent" to allow expert testimony for "purposes of obtaining explanation of the technical meaning of terms used in industry..."); *Toren v. Braniff, Inc.*, 893 F.2d 763, 766 (5th

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[32] Although the case did cite the Sixth Circuit case of *Abney v. Amgen, Inc.*, 443 F.3d 540, 551 (6th Cir.2003) for support of its holding, *Abney* was decided principally under Maryland law.

[33] The Texas cases Abbott relegated to FN 32 of its motion are equally unenlightening: *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 742 (N.D. Tex. 2000)(Court's ruling concerned the learned intermediary causation analysis in a medical device case and whether an "objective" standard applied to the learned intermediary analysis; no discussion regarding drug company duty to adequately warn doctors or patients in clinical trial context.); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543 (3d Cir. 1994)(Dicta in the context of a preemption discussion in a medical device adulteration case in which plaintiff offered no proof to support "vague" allegation of failure of device manufacturer to adequately inform the physician.); *Anderson v. George H. Lanier Mem'l Hosp.*, 982 F.2d 1513, 1517 (11th Cir. 1993)(Medical device case concerning fraud, no physical injuries, and no allegations that device manufacturer failed to apprise study monitor or patients of risks.).

Cir. 1990)(Looking favorably on expert witness industry custom testimony in airline industry.).[34] With regard to expert testimony, there is simply "no blanket prohibition in the Fifth Circuit regarding particular industry standards and practices." *Enniss Family Realty I, LLC v. Schneider Nat. Carriers, Inc.*, 3:11CV739-KS-MTP, 2013 WL 30137,11 (S.D. Miss. Jan. 2, 2013).

In rendering his opinions regarding industry custom, Dr. Hamrell employed the same reliable, analytical methodology he employed in rendering his other opinions in this case. Dr. Hamrell discussed his opinions regarding the "standard practice in the industry" within the body of his report. Exhibit 2 at 12-13; 17-18. He discussed his methodology and how he defines "standard of practice" in deposition. Exhibit 5 at 80-18-81:8.[35] Moreover, with respect to the "standard of care" issue, Dr. Hamrell used FDA regulations on labeling as his "objective standards" for his standard of practice opinions. Exhibit 3 at 93:9-94:19. Dr. Hamrell identified the basis, both factual and regulatory, for his opinions. Exhibit 2 at 9-10; 16 ("...had substantial information that could have been used to present a clearer picture of the risks...Abbott did not use these methods to properly inform doctors about risks of lymphoma...standard practice in industry when significant new safety information is added..."); *Id.* at 16-18 (discussing relevant statutes, means available to Abbott to disseminate

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[34] *See also, Tietz, supra,* Exhibit 1 at 43-44 (Allowing Dr. Hamrell to opine on Abbott's conduct *vis-à-vis* standard of care in Humira personal injury case.); *Pelletier v. Main St. Textiles, LP*, 470 F.3d 48, 55 (1st Cir. 2006)("...the customs and practices of an industry are proper subjects for expert testimony."); *Bartlett, supra,*742 F. Supp. 2d at 195; *Kellogg v. Wyeth*, 2012 WL 2970621 (D. Vt. July 20, 2012)(Allowing expert testimony as to appropriate standard of care for a pharmaceutical company under similar circumstances including responsibility for accuracy of product label and what a reasonable pharmaceutical company would have done under similar circumstances); *Baldonado v. Wyeth, No. 04 C 4312,* 2012 WL 1802066, at 8 (N.D. Ill. May 17, 2012) (rejecting *Daubert* challenge to the reliability of the expert's opinion on the applicable standard of care, reasoning that the expert "may reliably draw on his vast experience in this area, and his expert knowledge of federal and industry regulations, to opine on the standard of care"); *In re Yasmin and Yaz (Drospirenone) Mktg Litig*., MDL No. 2100, 2011 WL 6740391, at 12 (S.D. Ill. Dec. 22, 2011) (Permissible for expert who is familiar with custom and practice in the industry to opine on whether pharmaceutical company's actions comported with industry standard.); *Harms v. Lab. Corp. of Am.*, 155 F. Supp. 2d 891, 903-04 (N.D. Ill. 2001)("In this case, testimony on the general standards of care in the industry would come from Chapman's professional knowledge...This is classic expert testimony.").

[35] In FN34 of its motion, Abbott completely usurps the record in an effort to discredit Dr. Hamrell. The man simply used the wrong word in his *Calisi* report and corrected it in deposition. He corrected his typo in both the report and deposition in this case. *Id.*; Exhibit 2 at 18.

warning information to doctors, internal Abbott documents and company testimony that showed an internal appreciation of a greater risk than was being described to doctors, and the inconsistency in Abbott's actions.).

And unlike *Kaufman v. Pfizer Pharmaceuticals, Inc.*, 1:02-CV-22692, 2011 WL 7659333 (S.D. Fla. Aug. 4, 2011) where the proffered expert never tied the facts of the case to her warnings opinion, Dr. Hamrell makes clear that it is the confusing nature of the information in the label that made it substandard. Exhibit 3 at 227:4-227:20; 230:11-15. ("It's the way the information is expressed that makes it confusing in order for someone to interpret it."):

> Q I'm sorry. By including in the label the data across indications, is it your opinion that Abbott has violated the standard of care?
>
> A The data itself does not violate the standard of care. It just makes it difficult for someone to interpret and understand when the data are pooled together without separating out the risk of lymphoma in the different populations. You are trying to focus on rheumatoid arthritis combined --RA patients with a number of other indications makes it hard for a physician to differentiate what the true risk is in an RA patient.

Id. at 227:4-227:20; 230:11-15.

Abbott focuses on FDA action with respect to its criticisms regarding his standard of care opinion. However, they ignore the fact that it is always the pharmaceutical company, not the FDA, who is responsible for the content of its labeling.[36] This type of backdoor preemption argument has nothing to do with methodology. What FDA did or did not do is singularly unimportant in this context. Rather, Dr. Hamrell's focus is on what *Abbott did or did not do* based on his extensive industry experience, knowledge of FDA regulations, and review of *Abbott* documents and personnel testimony. Exhibit 2 at 14-18 and citations therein.

[36] *See* FN 30, *supra.*

Specific to this case, part of Dr. Hamrell's methodological approach was to examine what other steps Abbott had, or could have, taken with respect to warning about this risk. Abbott's failure to utilize any of these vehicles, and more importantly, to specifically tell its sales representatives not to mention lymphoma to doctors, unless asked, are inconsistent with industry practice and regulation. *Id*. at 17-19 (citing internal Abbott documents). Failure to act outside the label is an important component of Dr. Hamrell's opinions in this case. While Abbott claims he did not employ a sound methodology, Dr. Hamrell applied the facts of this case to his specialized and extensive regulatory experience to come to his conclusions. This is appropriate and reliable under *Daubert/Kumho*.

Abbott further misleads the Court when it attempts to mischaracterize Dr. Hamrell's opinions concerning Abbott's conduct as "motive" and "state of mind." The fact of the matter is that no such opinions have been offered. Rather, Dr. Hamrell's opinions are focused on industry practice and are based on an objective review of Abbott's *internal documents* and sales representative activities. *Id.* at 13 ("Humira label failed to provide adequate information to doctors and patients..."); 15 ("...company was aware of reasonable evidence...Dr. Medich...admitted that [data] indicate[d] an increased rate of malignancies...not included in the initial label"); 16-17 (failed to use sales representatives and "Dear Healthcare Provider letters" to apprise of risk; sales representatives and company officials focused on favorable literature to the exclusion of risk information; chose not to inform doctors unless they were asked); 17 (marketing activities inconsistent with company scientist testimony regarding telling doctors about risk...Abbott failed to use available methods"). Further, in deposition Dr. Hamrell specifically stated he had no opinion on any particular Abbott motive, reason, or state of mind for any of Abbott's actions. Exhibit 5 at 81:10-82:20. He was simply commenting on its failure to clearly apprise doctors of the specific risk at issue despite the means and ability to do so. And this failure is contrary to industry custom.

Moreover, Dr. Hamrell's opinions are not legal conclusions. Nowhere does he use any legal term of art, or otherwise infringe on the role of the judge or jury. As this Court has written, "[u]nder Rule 704(a), "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." *Hixson v. Houston Indep. Sch. Dist.*, 4:09-CV-3949, 2011 WL 3648104 (S.D. Tex. Aug. 17, 2011) *reconsideration denied,* 4:09-CV-3949, 2011 WL 4860004 (S.D. Tex. Oct. 13, 2011). Dr. Hamrell's opinions do not touch upon or otherwise comment on legal conclusions to be drawn from the evidence. Rather, they synthesize the relevant regulations through the prism of industry custom to reach a conclusion as to whether Abbott's conduct was consistent with the industry norm. Such testimony is perfectly permissible.

Finally, a word about *In re Byetta Cases*, Slip.Op., JCCP No. 4574 (Calif. Super. Ct. Jan. 27, 2012). It is true the court in *Byetta* excluded a *portion* of Dr. Hamrell's proffered opinions. However, the Court should be mindful of a few things. One, Dr. Hamrell was found qualified and allowed to opine regarding the FDA and regulatory activities concerning the drug at issue. *Byetta* at 4-5. Further, the "communication" opinions that were excluded concerned general causation, the defendant drug makers motives/state of mind, ethics, and misrepresentation to FDA/healthcare providers. *Id.* at 5-11. Dr. Hamrell is offering no such opinions in this case.

Conclusion

For all the reasons contained herein as well as in the concurrently filed companion oppositions referenced above, Abbott's Motion to Exclude the Testimony of Dr. Hamrell should be in all respects denied.

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Respectfully submitted,

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Certificate of Service

I certify that on this 30th day of July, 2013, Plaintiff's Response in Opposition to Defendant's Motion to Exclude the Testimony of Michael Hamrell, Ph.D. has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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